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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone 510-769-3010

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-52354

July 13, 1998

Mr. Raymond R. Kamradt
Properpak
6255 South Mojave Road, unit G
Las Vegas, Nevada 98120

# WARNING LETTER

Dear Mr. Kamradt:

An inspection of your veterinary drug manufacturing facility by FDA Investigator Anthony E. Keller on June 25 through 30, 1998, revealed significant deviations from the Good Manufacturing Practices (GMP's) for Finished Pharmaceuticals as established under Title 21, Code of Federal Regulations, Part 211. Such deviations cause veterinary drugs manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

Our inspection revealed multiple GMP deficiencies, including: no written procedures, no batch records, inadequate master production records, no record of testing/inspecting components or finished product, no record of cleaning the manufacturing equipment, no written specifications for finished products, no stability testing, no traceability of distributed lots, and no microbial testing of the deionized water.

Causing the adulteration of drugs after receipt in interstate commerce and delivering for introduction into interstate commerce of any article in violation of Section 512 are violations of Section 301(k) of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are met. Should you fail to promptly correct these violations, the Food and Drug Administration is prepared to invoke regulatory and/or administrative sanctions provided under the law. These include but are not limited to seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Karen L. Robles, Investigator, U.S. Food and Drug Administration, 801 I Street Room 443, Sacramento, California 95814.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District